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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jurgen Engel

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07/20/2010

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EXAMINER

CARTER, KENDRA D

ART UNIT

PAPER NUMBER

1627

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/523,455	<b>Applicant(s)</b> ENGEL ET AL.	
	<b>Examiner</b> KENDRA D. CARTER	<b>Art Unit</b> 1627	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 February 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-9 and 16-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-9 and 16-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 10, 2010 has been entered.

The Examiner acknowledges the applicant's remarks and arguments of February 16, 2010 made to the office action filed August 14, 2009. Claims 1, 4-9 and 16-28 are pending. Claims 4-9 and 16-25 are amended, and claims 26-28 are new. Claim 1 is cancelled.

For the reasons in the previous office action and below, the Applicant's arguments of the following rejections were found not persuasive and thus upheld: 1) the 35 U.S.C. 103(a) rejection of claims 1, 4, 5, 7, 16, 18, 21 and 25 as being unpatentable over Felberbaum et al. or Albano et al. or Engel et al. or Olivennes et al. in view of Ziegler et al., in further view of Hall et al.; 2) the 35 U.S.C. 103(a) rejection of claims 22-24 as being unpatentable over Felberbaum et al. or Albano et al. or Engel et

Art Unit: 1627

al. or Olivennes et al. in view of Ziegler et al., in further view of Hall et al. as applied to claims 1, 4, 5, 7, 16, 18, 21 and 25 above, and further in view of Garfield et al.; 3) the 35 U.S.C. 103(a) rejection of claims 6, 8, 9, 17, 19 and 20 as being unpatentable over Felberbaum et al. or Albano et al. or Engel et al. or Olivennes et al. in view of Ziegler et al., in further view of Hall et al. as applied to claims 1, 4, 5, 7, 16, 18, 21 and 25 above, and further in view of Deghengi et al. or Rabasseda et al.; 4) the obviousness-type double patenting rejection of claims 1, 4-9, 16-21 and 25 as being unpatentable over claims 1-6 of U.S. Patent No. 6,319,192 in view of Ziegler et al., Hall et al., Deghengi, Rabasseda et al. and Kent. The above rejections have been modified to include the amendments to the claims and new claims.

The new and modified rejections are below. The Applicant's arguments are addressed below.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 recites the limitation "wherein said ovarian stimulation is achieved" in claim 28. There is insufficient antecedent basis for this limitation in the claim. For compact prosecution, the Examiner examined claim 23 to be dependent on claim 26.

Claim 24 recites the limitation "wherein ovarian stimulation is achieved" in claim 28. There is insufficient antecedent basis for this limitation in the claim. For compact prosecution, the Examiner examined claim 24 to be dependent on claim 26.

Claim 25 recites the limitation "wherein said assisted reproduction techniques comprises" in claim 28. There is insufficient antecedent basis for this limitation in the claim. For compact prosecution, the Examiner examined claim 25 to be dependent on claim 26.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**(1) Claims 4, 5, 7, 16, 18, 21, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over (i) the article by Felberbaum et al. (of record) or Olivennes et al (of record), in view of (ii) Ziegler et al. (of record), and further in view of (iii) Hall et al. (of record).**

Felberbaum et al. teaches that GnRH antagonists such as Cetrorelix and Ganirelix can be administered in an IVF program to avoid premature LH-surges (see summary, in particular), thus teaching administering a first dose regimen of an LHRH antagonist of claims 16 and 18. Felberbaum et al. teaches that patients are treated with HMG starting on day 2 (see summary, in particular), and thus teaches administering a follicle stimulating compound during follicular phase, wherein said follicle stimulating compound stimulates ovarian follicle growth in claim 26, 21 and 28. Felberbaum et al. teaches that the patients are administered cetrorelix from day 7 until induction of ovulation with HCG, and thus teaches suppression of premature ovulation by administering the LHRH-antagonist during the follicular cycle as in claim 26, 5 and 27; and induction of ovulation with HCG as in claim 26 (see summary, in particular.) Felberbaum et al. also teaches performing IVF (i.e. assisted reproduction techniques), as claims 26 and 25 (see summary in particular.) Thus, Felberbaum et al. teaches a method for programming an infertility treatment cycle having the following steps of claim 26: 1) administering a first dose regimen of an LHRH antagonist of claims 16 and 18, wherein LHRH induces a luteal regression; 2) administering a follicle stimulating compound during said follicular phase, wherein said follicle stimulating compound stimulates ovarian follicle growth with the compound from claims 21 and 28; 3) administering a second dose regimen of said LHRH antagonist from claims 16 and 27 during said follicular phase, wherein said second dose regimen of an LGRH antagonist

suppresses premature ovulation; 4) inducing ovulation by administering HCG; and 5) applying assisted reproduction techniques.

Olivennes et al. teaches providing a GnRH antagonist such as cetrorelix to prevent premature LH surges in an IVF-ET program (see abstract, in particular.) Olivennes et al. teaches that controlled ovarian hyperstimulation (COH) is carried out with HMG on day 2 of the menstrual cycle, with cetrorelix being administered during the hyperstimulation (follicular phase) (see abstract, in particular.) Olivennes et al. teaches that ovulation is triggered by administration of HCG (see paragraph bridging pages 469-470, in particular.) Thus, Olivennes et al. a method for programming an infertility treatment cycle having steps (c)-(f) as recited in claim 1. *Thus, Olivennes et al. teaches a method for programming an infertility treatment cycle having the same steps as Felberbaum et al. for claim 26 above.*

The references do not specifically teach determining a luteal phase of a first menstrual cycle or determining a follicular phase of a second menstrual cycle wherein said second menstrual cycle immediately succeeds said first menstrual cycle in claim 26. The references further do not specifically teach terminating administration of the LHRH antagonist prior to the onset of menses in claim 26; luteal regression; or wherein the programmed menstrual cycle is programmed on a day that permits the assisted reproduction techniques to be carried out during routine operations of laboratories, clinics, or other assisted reproduction facilities (claim 4).

Ziegler et al. teaches the desirability of permitted advanced timing of the onset of controlled ovarian hyperstimulation (COH) (see page 561, right hand column, in particular.) Ziegler et al. teaches that it is difficult to properly time the onset of HMG administration (see introduction, in particular.) Ziegler et al. teaches that treatments were devised to improve scheduling of treatments for patients and team members by synchronizing FSH rises *that initiate new menstrual cycles* with the onset of HMG administration for COH (see page 563, left hand column, in particular.) Ziegler et al. teaches that oestradiol was used for timing the follicular phase increase in FSH to provide for the onset of HMG treatment (see discussion, first full paragraph, in particular), and further teaches that advanced programming of COH has been previously achieved with oral contraceptives (see paragraph bridging pages 563-564, in particular.) Ziegler et al. teaches that the oestradiol treatment was started 7.1 days before the onset of menses (luteal phase) and continued for 5 days thereafter (see results section, in particular.) Since a new menstrual cycle initiates with the onset of HMG administration, it is understood that the administration of the second dose of LHRH antagonist in Felberbaum et al. and Olivenness et al. are in the second menstrual cycle. Thus, Ziegler et al. teaches the desirability of permitting the advanced timing of COH treatments by starting the administration of a composition during the luteal phase of one period and to allow for advanced scheduling of treatments to the next period (i.e. determining a luteal phase and a follicular phase of *a second menstrual cycle, and the*



*motivation to administer an LHRH antagonist in a first menstrual cycle and again in a second menstrual cycle immediately succeeding the first).*

Hall et al. teach that administration of a GnRH antagonist (LHRH antagonist) in the mid-luteal phase results in luteolysis (see abstract, in particular.) Hall et al. teaches that three daily antagonist injections begun on day 4 or 5 after ovulation (luteal phase) resulted in menstrual bleeding within 24-48 hrs of the final day of the antagonist administration (see page 997, MLP studies, left hand paragraph, in particular.) Thus, Hall et al. teaches terminating administration of the LHRH antagonist prior to the onset of menses (claim 26), administration of an LHRH antagonist during the luteal phase of the preceding menstrual cycle (claim 26), and a determining/programming the menstrual cycle (claim 26). Hall et al. teaches that seventy two hours of gonadotropin deprivation (due to GnRH antagonist administration) in the luteal phase resulted in prompt luteolysis in all subjects (see page 998, final paragraph, in particular.) Hall et al. further teaches that in human studies, complete luteolysis is demonstrated in response to GNRH antagonism (see page 999, left hand column first full paragraph, in particular.) Thus, Hall et al. teaches that administration of a GnRH antagonist during the luteal phase results in luteolysis and shortening of the luteal phase (i.e. inducing a luteal regression; addressing claim 26).

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide advanced timing as taught by Ziegler et al. with the assisted reproductive techniques involving administration of HMG and ovarian stimulation such as COH of Felberbaum et al, Albano et al, Engel et al. and Olivennes et al, because the references teach assisted reproductive techniques involving stimulation with HMG prior to induction of ovulation with HCG, whereas Ziegler et al. teaches that a COH treatment involving HMG ovarian stimulation can be improved by providing advanced timing via administration of a composition to allow for improved scheduling of treatments. Thus, one of ordinary skill in the art would have found it obvious to combine the advanced timing method with the assisted reproductive techniques of Felberbaum et al. or Olivennes et al. with the expectation of improving the efficiency of treatment scheduling and thus fertilization success with the advanced timing method.

Accordingly, one of ordinary skill in the art would have found it obvious to provide the GnRH antagonist (LHRH antagonist) of Hall et al. in the advanced timing method of assisted reproductive techniques of Felberbaum et al, Albano et al, Engel et al, Olivennes et al. and Ziegler et al, because Ziegler et al. teaches the desirability of providing controlled timing to allow for better scheduling of procedures and thus better effectiveness of the procedures, such as by controlling the menstrual cycle via oral contraceptives, whereas Hall et al. teaches compositions that control the length and duration of the menstrual cycle, to increase the rate of luteolysis and decrease the

Art Unit: 1627

duration of the luteal phase. Thus, one of ordinary skill in the art would have found it obvious to provide the composition Hall et al, in the method of Felberbaum et al. or Olivennes et al. and Ziegler et al, with the expectation of providing control of the menstrual phases to provide advanced timing for the assisted reproductive techniques. Thus claim 26 is obvious over the recited references.

Regarding claim 4, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the days on which the compositions are provided, according to the guidance provided by the references, to provide the advanced timing and scheduling of the assisted reproductive techniques. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233,235 (CCPA 1955.)

Regarding claim 7, Felberbaum et al. teaches administration of cetrorelix or ganirelix as a GnRH antagonist (i.e. LHRH antagonist) for the first dose administration, and cetrorelix for the second dose administration of the LHRH antagonist. Thus one skilled in the art would be able to choose from known comparable LHRH antagonist to administer either for the first or second administration of the LHRH antagonist.

**(2) Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over (i) the article by Felberbaum et al. (of record) or Olivennes et al (of record), in**

**view of (ii) Ziegler et al. (of record), and further in view of (iii) Hall et al. (of record), as applied to claims 4, 5, 7, 16, 18, 21, and 25-28 above, and further in view of Garfield et al (of record).**

Felberbaum et al., Olivennes et al, Ziegler et al. and Hall et al. are applied as discussed above, and teach assisted reproductive techniques involving a step of inducing ovulation with HMG (a gonadotropin), as discussed above. The references do not specifically teach inducing ovulation with the particular compounds that are clomiphene, a combination of antioestrogens and gonadotropins or a combination of clomiphene with gonadotropins, as in claims 22-24.

Garfield et al. teaches that clomiphene is a non-steroidal antiestrogen that stimulates ovulation by stimulating follicle growth and maturation (see column 3, lines 9-20, in particular.)

Accordingly, it is considered that one of ordinary skill in the art would have found it obvious to incorporate clomiphene into the assisted reproductive techniques as discussed by the references, either alone or in combination with a gonadotropin such as HMG, because Garfield et al. teaches that clomiphene is an antiestrogen that stimulates follicle growth and ovulation, whereas the Felberbaum et al. or Olivennes et al. and Hall et al. references teach that HCG (a gonadotropin) is provided to induce ovulation, as discussed above. Thus, one of ordinary skill in the art at the time the invention was

made would have found it obvious to combine the clomiphene with the above-described assisted reproductive techniques using the gonadotropin HCG with the expectation of providing suitable stimulation and induction of ovulation for the assisted reproductive techniques.

**(3) Claims 6, 8, 9, 17, 19, 20 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over (i) the article by Felberbaum et al. (of record) or Olivennes et al (of record), in view of (ii) Ziegler et al. (of record), and further in view of (iii) Hall et al. (of record), as applied to claims 4, 5, 7, 16, 18, 21, and 25-28 above, and further in view of (iv) Deghengi et al (of record) or Rabasseda et al (of record.)**

Felberbaum et al., Olivennes et al, Ziegler et al. and Hall et al. are applied as discussed above, and teach providing a GnRH antagonist (LHRH antagonist) such as cetrorelix or ganirelix in the therapeutic fertility management technique as recited in claims 5, 16, 18 and 26. The references do not specifically teach providing teverelix, antide or abavelix, as recited in claims 6, 8-9, 17, 19-20 and 27.

Dehgenghi teaches that cetrorelix, teverelix, ganirelix and antide are known to be LHRH antagonists (GnRH antagonists) (see column 2, lines 19-23, in particular.) Rabasseda et al teaches that LHRH-antagonists (GnRH antagonists) such as cetrorelix, ganirelix and abarelix are known to be useful in the treatment of female infertility (see

Art Unit: 1627

introduction and Table 1 of page 397, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the antagonists of Deghenghi or Rabasseda et al. in the method of Felberbaum et al, Olivennes et al, Ziegler et al. and Hall et al, with the expectation of providing a suitable GnRH antagonist (LHRH antagonist) in the method. Since, Felberbaum et al. teaches administration of cetrorelix or ganirelix as a GnRH antagonist (i.e. LHRH antagonist) for the first dose administration, and cetrorelix for the second dose administration of the LHRH antagonist, one skilled in the art would be able to choose from known comparable LHRH antagonist to administer either for the first or second administration of the LHRH antagonist.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

Art Unit: 1627

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4-9, 16-21 and 25-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,319,192 to Engel et al. in view of the Ziegler et al, Hall et al, Dhegenghi, Rabasseda et al and Kent (4,016,259 of record) references as applied above.

The instant claims differ from those in the patented case because the patented case only recites providing an LHRH- antagonist with stimulation of ovarian follicle growth, ovulation induction and intrauterine insemination, whereas the instant case further recites a programming step involving the LHRH antagonist or a progestogen composition.

However, the combination of such a programming method with an infertility treatment is obvious over the teachings of Ziegler et al, Hall et al, Dhegenghi, and Rabasseda et al. as discussed for claims 4-9, 16-21 and 25-28 in the 103(a) rejection made above. Kent discloses that the combination of progestogens and estrogen, i.e., mestranol and ethinylestradiol is useful in animal contraception (see col.1 lines 20-25). Accordingly, the instant claims are not patentably distinct from those in the patented

case.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive.

The Applicant re-alleges their previously presented arguments. Particularly, the Applicant argues that the amended claims are not taught by the cited references. Particularly, administration of an LHRH antagonist during the luteal phase of the first menstrual cycle wherein said LHRH administration induces a luteal regression, and a second cycle as immediately following the first cycle is not taught. The Applicant's hold in abeyance the double patenting rejections which may be addressed by means of a terminal disclaimer.

The Examiner disagrees because the teaching of administering an LHRH antagonist during the luteal phase is taught specifically by Felberbaum et al. or Olivennes et al. The distinction between the first period and the second period is taught by Zeigler et al. Particularly, Ziegler et al: teaches that treatments were devised to improve scheduling of treatments for patients and team members by synchronizing FSH rises *that initiate new menstrual cycles* with the onset of HMG administration for COH (see page 563, left hand column, in particular.) Ziegler et al. teaches that oestradiol was used for timing the follicular phase increase in FSH to provide for the onset of HMG treatment (see discussion, first full paragraph, in particular), and further teaches that advanced programming of COH has been previously achieved with oral contraceptives (see paragraph bridging pages 563-564, in particular.) Ziegler et al. teaches that the



Art Unit: 1627

oestradiol treatment was started 7.1 days before the onset of menses (luteal phase) and continued for 5 days thereafter (see results section, in particular.) Since a new menstrual cycle initiates with the onset of HMG administration, it is understood that the administration of the second dose of LHRH antagonist in Felberbaum et al. and Olivenness et al. are in the second menstrual cycle. Thus, Ziegler et al. teaches the desirability of permitting the advanced timing of COH treatments by starting the administration of a composition during the luteal phase of one period and to allow for advanced scheduling of treatments to the next period (i.e. determining a luteal phase and a follicular phase of *a second menstrual cycle, and the motivation to administer an LHRH antagonist in a first menstrual cycle and again in a second menstrual cycle immediately succeeding the first*). Further, Hall et al. provides the teachings of administering an LHRH antagonists in the preceding menstrual cycle, and termination of administration of an LHRH antagonist prior of the onset of menses.

The teaching of the LHRH antagonist promotes luteal regression is provided by Hall et al. Particularly, Hall et al. teach that seventy two hours of gonadotropin deprivation (due to GnRH antagonist administration) in the luteal phase resulted in prompt luteolysis (i.e. structural and functional degradation of the corpus luteum that occurs at the end of the luteal phase) in all subjects (see page 998, final paragraph, in particular.) Hall et al. further teaches that in human studies, complete luteolysis is demonstrated in response to GNRH antagonism (see page 999, left hand column first

Art Unit: 1627

full paragraph, in particular.) Thus, Hall et al. teaches that administration of a GnRH antagonist during the luteal phase results in luteolysis and shortening of the luteal phase (i.e. inducing a luteal regression; addressing claim 26). Further, the same LHRH antagonist is administered by the Applicant's and the prior art. "Products of identical chemical composition can not have mutually exclusive properties." Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

### ***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:00 pm.

Art Unit: 1627

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kendra D Carter/  
Examiner, Art Unit 1627

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627

